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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,644	07/15/2003	Tomohiro Kodera	239568US0CONT	9003

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EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,644	KODERA ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *1 and 3-5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is the first action on the merits with claims 1-8 pending and under consideration. The Examiner would like to point out for the record that all claims are viewed as having "closed language" regarding peptide content for examination purposes. This point is made because claim 1 is limited by language to the five peptides; thus, although claim 2, and 5-6 read "comprising", they still depend from claim 1 and were examined insofar as they are limited to the peptide content (closed language) of claim 1.

Specification

1. The abstract of the disclosure is objected to because the abstract begins without capitalizing the first letter of the first word of the abstract. Furthermore, the abstract of the disclosure is objected to because the abstract recites amino acid sequences without the sequence identifying numbers. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: page 4, line 28, in the brief description of figure 5, Applicants failed to insert the black circle in the parenthesis.

Appropriate correction is required.

Claim Objections

3. Claims 1 and 3-5 are objected to because of the following informalities:

a) Claim 1 is objected to for the use of the term "formula" in describing more than one amino acid sequence wherein the plural form of formula is required:

b) Claim 1 objected to for failing to provide a sequence identifier for each individual sequence of formulae (1)-(5).

(c) Claim 1 objected to for failing to use *alternative language* in listing the formulae (1)-(5).

(d) Claim 3 is objected to for the use of "The" to start the claim wherein the sentence should start with the term "A" since there is nothing to which the claim is referring for purposes of introduction.

(e) Claim 4 is objected to for the use of "The" to start the claim wherein the sentence should start with the term "A" since there is nothing to which the claim is referring for purposes of introduction. And, claim 4 is objected to for the use of "D3" for the first time in the claim set without a full representation of what "D3" actually is, e.g., Applicants should consider "protease D3".

(f) Claim 5 is objected to the use of the term "salts" in the plural wherein the term should be used in the singular form.

Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written

Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is "*whatever is now claimed*" (see page 1117).

A review of the language of the claims indicates that these claims are drawn to a genus, i.e., angiotensin inhibitors.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

The genus claimed is not supported by the specification in that the specification is to *angiotensin converting enzyme inhibitors* and not to "angiotensin inhibitor(s)". Even though

claim 2 is dependent upon claim 1 which would lend some structure to the claimed complex, it is not sufficient regarding the activity of such a complex; especially where an angiotensin converting enzyme inhibitor is complexed with an angiotensin inhibitor thus yielding a complex that would nullify each other's component functions. Therefore, there is no written description as to structure or function in the specification that would demonstrate to those skilled in the art that at the time of filing that applicants were actually in possession of the claimed invention. The present claims encompass numerous species that are not further described. There is substantial variability among the possible species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises angiotensin inhibitors. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

(a) Claim 4 lacks those steps for getting to the hydrolyzing step and then to the point of isolation of the desired product, e.g., the peptides of formulas 1-5. On pages 7 and 8 of the specification Applicants state that there required isolation methods to get the

desired angiotensin converting enzyme inhibitor; consequently, since claim 4 is drawn to production of angiotensin converting enzyme inhibitors, it is indefinite from the recited method steps of claim 4 as to how Applicants went from the hydrolyzing to the isolated angiotensin converting enzyme inhibitors.

(b) Claims 7-8 lack those reasonable steps for getting to the elements required to be in place for the hydrolyzing of soy(bean) protein and then isolating the desired product. On pages 7 and 8 of the specification Applicants state that there required isolation methods to get the desired peptides of formulas 1-5; consequently, since claims 7-8 are drawn to production of the claim 1 peptides of formulas 1-5, it is indefinite from the recited method steps of claims 7-8 as to how Applicants went from the hydrolyzing to the isolated peptides of formulas 1-5.

8. Claims 2, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected for the indefiniteness wherein according to the specification the sequences disclosed in claim 1 refer to inhibitors of angiotensin converting enzyme, not to inhibitors of angiotensin as claimed in claim 2.

Claims 2 and 6 are rejected for the indefinite recitation that the product of from both claims 2 and 6 *comprise* "the peptides according to claim1 or the salts thereof." It is unclear if Applicants intend for all sequences (1)-(5) to be in the claimed products of claims 2 and 6, or alternatively, only one peptide from sequences (1)-(5) to be in the desired products or mixtures of the different sequences (1)-(5).

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Kodera *et al.* (US 6,455,273 B1).

Kodera *et al.* teaches methods of making a consumable product wherein the method steps includes contacting a soybean protein with a thiol protease D3 obtainable from germinating soybean cotyledons to produce a protein hydrolysate with less bitterness (see claims 1, 3 and 9). This anticipates the instantly claimed method steps of claims 4 and 7-8, wherein claims 4 and 7-8 are drawn to one method step which is disclosed in Kodera *et al.* and that is hydrolyzing with a D3 protease. Subsequently, since the instant methods steps are identical to those method steps disclosed by Kodera *et al.*, in patent claims 1, 3 and 9, the products obtained by the Kodera *et al.* methods anticipate the products of the instantly claimed invention, e.g., the peptides of formulas 1-5, also the food product of claim 6 and the anti-hypertensive of claim 5. Since the products of the US Patent and the instant application are identical, their activities are inherently the same. Therefore, the products of both the US Patent claims 1, 3, and 9 and the instant claims are identical with identical activities, for example the activity is that as an angiotensin converting enzyme inhibitor (see instant claims 2 and 3) and anti-hypertensive (see instant claim 5) agent as instantly claimed.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

10. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Kodera *et al.* is applied here in light of Applicants' lack of perfecting the priority claim to the foreign Japanese applications: Japan 2001-007400 and Japan 2001-308974. These foreign documents have not been translated; therefor, Applicants' priority is limited to that of the PCT/JP02/00194 from which the instant application is a continuation.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 9 of U.S. Patent No. 6,455,273 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the base claim 1 of the reference recites the use of a thiol protease and a protein to produce the desired protein hydrolysate. The patent claims, as limitations, the protease D3 and

the protein as soybean protean. Therefore, one would be motivated to use the D3 protease to hydrolyze the soybean protein because the use of such method components would lead to the desired soybean hydrolysate peptide products.

Claims 1-8 are directed to an invention not patentably distinct from claims 1, 3 and 9 of commonly assigned US Patent 6,455,273 B1 or distinct from the products of those method claims 1, 3 and 9. Specifically, the base claim 1 of the US Patent recites the use of a thiol protease and a protein to produce the desired protein hydrolysate. The US Patent claims, as limitations, the protease D3 (patent claim 3) and the protein as soybean protean (patent claim 9). Therefore, one could readily envisage the use of D3 protease to hydrolyze the soybean protein because the use of such method components would lead to the desired soybean hydrolysate peptide products as indicated in patent base claim 1. One could readily envisage the use of D3 protease and soybean protein because they are specifically claimed embodiments (see claims 1, 3 and 9). Thus, the method steps just explained anticipate the instantly claimed method steps of claims 4 and 7-8 by using a protease inhibitor (D3) in claims 4 and 7-8. Additionally, as presented in the instant method claims 4 and 7-8, the claims are the same as those claimed in the US Patent (claims 1, 3 and 9), thus, one would expect the product from the same method steps to be the same products, e.g., the peptides of formulas 1-5 (claim 1), angiotensin converting enzyme inhibitor (claims 2 and 3), the anti-hypertensive of claim 5, and the making of a food product as in claim 6.

13. The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned US Patent 6,445,273 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained

from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism

PATENT EXAMINER